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Why Did Pfizer Halt COVID Vaccine Clinical Trials for Pregnant Women?

In 2021, when the Centers for Disease Control and Prevention — without any evidence of safety — authorized the mRNA shot for pregnant women and anyone 6 months and older, Pfizer suddenly stopped its randomized trial for pregnant women. The vaccine maker has yet to disclose its study data.

By **Dr. Joseph Mercola**

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Story at a glance:

- In February 2021, Pfizer launched a randomized, placebo-controlled, observer-blind study to evaluate the safety of its COVID-19 shot — BNT162b2 — in healthy pregnant women.
- The injections were set to take place between 24 and 34 weeks gestation, with participants randomized 1-to-1 to receive a COVID-19 shot or placebo.
- The study was initially set to enroll 4,000 women, but Pfizer only signed up 349, then stopped enrollment entirely.
- The Centers for Disease Control and Prevention's (CDC) widespread endorsement of COVID-19 shots for pregnant women before the study was completed may have negated the need for the trial.
- Pfizer stated that because so many pregnant women had already gone ahead and gotten the shot, due to the government's endorsement, enrollment dropped and there was no reason to move ahead with the study.

No randomized trial data are available for use of the COVID-19 shot in pregnant women, and Pfizer cut its pregnancy trial short.

But this doesn't stop the CDC from recommending COVID-19 injections for everyone 6 months and older, including "people who are pregnant, breastfeeding, trying to get pregnant now, or those who might become pregnant in the future."

"Not having any good data didn't seem to bother the CDC," Dr. Martin Makary, a professor at Johns Hopkins University School of Medicine, wrote in Tablet.

He and a team of scientists petitioned the U.S. Food and Drug Administration (FDA) to add a disclaimer to the shot's label about the lack of trial data on its safety in pregnant women. The FDA declined, stating that this information wouldn't be relevant.

Pregnant women, however, do need to know about the shot's lack of testing during pregnancy — it's the foundation of informed consent. They'd also likely be interested to know why Pfizer stopped its pregnancy trial early and has yet to make the results it did find public.

Pfizer stopped COVID jab pregnancy trial, withholds data

In February 2021 Pfizer launched a randomized, placebo-controlled, observer-blind study to evaluate the safety of its COVID-19 shot — BNT162b2 — in healthy pregnant women. The injections were set to take place between 24 and 34 weeks gestation, with participants randomized 1-to-1 to receive a COVID-19 shot or placebo.

But while the study was initially set to enroll 4,000 women, Pfizer only signed up 349, then stopped enrollment entirely.

"Most concerning," Makary explained, "the pregnancy outcomes of those who participated in the trial, and their babies, are still not public today, nearly two years later."

Pregnant and breastfeeding women were excluded from Pfizer's and Moderna's Phase 3 clinical trials, but in April 2021, CDC director Dr. Rochelle Walensky announced, "CDC recommends that pregnant people receive the COVID-19 vaccine."

The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine soon echoed this statement, recommending pregnant women get injected, as did the UK's Royal College of Obstetricians and Gynecologists.

So, as the months passed, hundreds of thousands of pregnant women globally rolled up their sleeves to receive the vaccine, despite the absence of any clinical trials.

"The message from authorities was clear — the harm from COVID-19 infection outweighed any harms from the mRNA vaccine — but in truth, they couldn't possibly have known," noted Maryanne Demasi, Ph.D., a former medical scientist with the University of Adelaide and former reporter for ABC News in Australia.

Animal studies show fetal loss, skeletal variations

Pfizer's product labeling suggested, "No vaccine-related adverse effects on female fertility, fetal development or postnatal development were reported."

But, Demasi reported, a freedom of information request from 2021 showed this was based on an animal study of just 44 rats, which showed concerning findings about fetal loss:

> "The study found the vaccine led to a statistically significant doubling in fetal loss (9.77% mRNA vs 4.09% saline), but Pfizer concluded that the difference between the two groups was 'not biologically meaningful.'
>
> "The label also states that Pfizer's mRNA vaccine was not tested for its potential to cause carcinogenicity (ability to cause cancer), genotoxicity (ability to damage genetic information), or impairment of male fertility."

An animal study conducted by Moderna also showed a significant number of rats were born with skeletal variations after their mothers were injected with the COVID-19 shot while pregnant.

But, according to Demasi, "Moderna concluded that the 'Skeletal variations are structural changes that do not impact development or function of a developing embryo' and therefore 'not considered adverse.'"

Trial stopped because many pregnant women already injected

Pfizer hasn't publicly explained why its trial on pregnant women was stopped short, nor why the resulting data hasn't been published. It's possible they ended the trial because of unfavorable results. It wouldn't be the first time.

However, in this case, it appears the CDC's widespread endorsement of COVID-19 shots for pregnant women — before the study was completed — may have negated the need for the trial altogether, at least from Pfizer's perspective.

As Makary put it:

> "In the case of the COVID vaccine trial in pregnant women, the trial may have been terminated not because the results were unfavorable, but because no data was needed. The medical and public health establishments had already made up their minds, declaring it safe and effective regardless of what the data was going to show. Why evaluate a product if the CDC and ACOG are already sold on the product?"

Demasi agreed.

In fact, she published an email from Pfizer, in which the company admitted that enrollment for their trial significantly declined at the end of 2021, because health officials had already given the shot their seal of approval.

Because so many pregnant women had already gone ahead and gotten the shot, due to the government's endorsement, there was no reason to move ahead with the study.

Demasi published Pfizer's email response, which reads:

> "In the fourth quarter of 2021, enrollment was stopped in C4591015 Study (a Phase 2/3 placebo controlled randomized observer-blind study to evaluate the safety, tolerability, and immunogenicity of BNT162b2 against COVID-19 in healthy pregnant women 18 years of age and older). This study was developed prior to availability or recommendation for COVID-19 vaccination in pregnant women.
>
> "The environment changed during 2021 and by September 2021, COVID-19 vaccines were recommended by applicable recommending bodies (e.g., ACIP in the U.S.) for pregnant women in all participating/planned countries, and as a result the enrollment rate declined significantly.
>
> "With the declining enrollment, the study had insufficient sample size to assess the primary immunogenicity objective and continuation of this placebo controlled study could no longer be justified due to global recommendations. This proposal was shared with and agreed to by FDA and EMA."

As for the lack of published data, Pfizer stated it doesn't have it:

> "Pfizer does not yet have a complete data set from the maternal immunization study, C4591015. Pfizer and BioNTech plan to complete the analysis of the clinical trial C4591015 and share it with global public health regulators and seek publication or presentation as is our standard practice.
>
> "It is important to note that relevant real-world evidence on the use of COVID-19 vaccines in pregnant women has been presented and published numerous times by various parties in multiple journals and forums."

Natural immunity is still being ignored

Not only does ACOG "strongly recommend" that pregnant women get a COVID-19 shot, but they also recommend a booster dose.

"Vaccination may occur in any trimester, and emphasis should be on vaccine receipt as soon as possible to maximize maternal and fetal health. This recommendation applies to both primary series and booster vaccination," ACOG states.

But missing from their information is data about natural immunity.

Research by Makary and colleagues, published in JAMA, showed that natural immunity to COVID-19 — achieved by prior infection, not an injection — was durable for about two years, suggesting it's longer lasting than any protection gained from a COVID-19 shot.

A systematic review and meta-analysis published in The Lancet also revealed natural immunity to be at least as effective as, and likely superior to, COVID-19 injections.

Health officials don't have the data from Pfizer's randomized trial of the shots in pregnant women. But rather than erring on the side of caution — especially for those with natural immunity — they're still recommending everyone get the shots.

Scientists warn pregnant women not to receive COVID shots

Not everyone's on board with health agencies' push for pregnant women to get injected.

"The pushing of these experimental COVID-19 vaccines globally is the greatest violation of medical ethics in the history of medicine, maybe humanity," Dr. James Thorp, a maternal-fetal medicine expert, told Tucker Carlson.

Thorp and colleagues published a preprint study that found striking risks to pregnant women who received the shots, along with their unborn babies.

The outcomes were so dire that the researchers concluded pregnant women should not receive COVID-19 shots until further research is completed.

"A worldwide moratorium on the use of COVID-19 vaccines in pregnancy is advised until randomized prospective trials document safety in pregnancy and long-term follow-up in offspring," they explained.

Compared to the flu vaccine, COVID-19 shots were associated with a significant increase in adverse events including:

- Menstrual abnormality
- Miscarriage
- Fetal chromosomal abnormalities
- Fetal malformation
- Fetal cystic hygroma
- Fetal cardiac disorders
- Fetal arrhythmia
- Fetal cardiac arrest
- Fetal vascular mal-perfusion
- Fetal growth abnormalities
- Fetal abnormal surveillance
- Fetal placental thrombosis
- Low amniotic fluid
- Fetal death/stillbirth

The data also revealed a 27-fold higher risk of miscarriage and a more than twofold increased risk of adverse fetal outcomes across six different categories, according to board-certified internist and cardiologist Dr. Peter McCullough.

NIH study confirms menstrual changes post-jabs

Delayed menstruation has also been confirmed following COVID-19 shots, according to a study published in Obstetrics & Gynecology — funded by the National Institute of Child Health and Human Development and the National Institutes of Health Office of Research on Women's Health.

The study involved 3,959 individuals between the ages of 18 and 45 years. Those who had not received a COVID-19 shot noted no significant changes in cycle four during the study compared to their first three cycles.

But those who received COVID-19 shots had longer menstrual cycles, typically by less than one day when they received the shots.

The European Union, meanwhile, has recommended that "heavy menstrual bleeding" be added as a side effect to mRNA COVID-19 shots.

Makary noted:

> "Here in the U.S. there's been no such update to product labeling. This lack of humility was also evident when healthy young women were told with incredible absolutism that the COVID vaccine cannot affect fertility. The right answer should have been: We don't think it will affect fertility but we don't have any good data on the question."

Officials choose 'stern paternalism' over informed consent

In the absence of data for a vulnerable population — pregnant and breastfeeding women — health officials should have urged caution.

As the effectiveness of natural immunity became clear, people should have been informed of this and warned of potential risks from COVID-19 shots. This way, they could make an informed decision before consenting to an injection that could have serious reproductive effects.

The Institute for Pure and Applied Knowledge felt the data were compelling enough in 2021 to withdraw the shots for vulnerable populations like pregnant women, but health officials chose, instead, to make them guinea pigs for an untested, experimental shot.

"In the absence of good data, organized medicine chose the path of stern paternalism. But in my experience as a physician, it's far better to properly inform a patient rather than steamroll their questions," said Makary.

If and when Pfizer does release the data, it's possible that health agencies will have some explaining to do if the data aren't favorable.

Makary continued:

> "It may be that Pfizer's pregnancy trial would have been favorable to the vaccine, showing that the benefits outweigh harms, but Pfizer has not released the data.
>
> "Perhaps the data was not favorable, or perhaps Pfizer realized they had convinced the medical establishment without data, so why run the risk of sharing what a placebo-controlled trial shows?"

Originally published by Mercola.

The views and opinions expressed in this article are those of the authors and do not necessarily reflect the views of Children's Health Defense.

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Dr. Joseph Mercola

Dr. Joseph Mercola is the founder of Mercola.com.

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Ricky Ricardo
4 days ago edited

Trick question? Here's a question for you...how much money would Big Pharma lose, if word got out that fetuses of pregnant women who were jabbed were dying? Can't kill the goose that lays the golden egg - only unborn babies! "Profit Before People" - that's the number one corporate rule.

11 0 Reply • Share ›

William H Warrick III MD
4 days ago

84% of women getting the Experimental Gene Therapy injection prior to the 22nd week have Spontaneous Abortions.

9 0 Reply • Share ›

GrouchyMathGrad → William H Warrick III MD
3 days ago

I don't think that's quite true. That's a statistic referring to "completed" pregnancies who's outcomes were known in one study, if I remember right.

Still, miscarriages go way up, birth defects go up, and lord only knows what kinds of problems these children will have going forward. I certainly hope the perpetrators of this crime against humanity will eventually face a noose - or more barbaric forms of capital punishment.

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Flora Flowers
4 days ago

It is unbelievable that any pregnant women would inject toxins to her body
It is crime they lied it was safe and effective

6 0 Reply • Share ›

el Gallinazo
4 days ago

Why Did Pfizer Halt COVID Vaccine Clinical Trials for Pregnant Women?

Because it was designed to be a bioweapon against humanity from the start, and particularly against fetuses. Sasha Latypova and Catherine Watts have proven this beyond doubt simply by following the FOIA dox trail. What Mercola appears to be ignorant of is that the glop shots were never "legally" marketed or purchased by the DoD as a medicine, vaccine, or "gene therapy," but rather as a nondescript "countermeasure" and thus only under the control of the DoD and not the FDA or CDC. The so-called trials were just kabuki theater to give the masses CON-fidence. Mercola still thinks that cv-1984 was a real disease and not an utter fabrication foisted upon the public by the greatest propaganda rollout in humanity's pathetic history..

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Ricky Ricardo → el Gallinazo
4 days ago

This entire society is one big PsyOps!

4 0 Reply • Share ›

Voyt Regnal → Ricky Ricardo
3 days ago

Hey Ricky:
Check NHPPA website please, read how they plan to fight Bill C-47 !
https://nhppa.org/

2 0 Reply • Share ›

Ricky Ricardo → Voyt Regnal
3 days ago

Thanks. Shawn does good work! This was all being planned decades ago. Their first move, was to take over Codex Alimentarius! I'll be buying some Molecular Hydrogen tablets soon. I've never tried them; although, if I get the results I'm hoping for, I'll be stocking up - big time!

1 0 Reply • Share ›

Flora Flowers → Ricky Ricardo
4 days ago

We are run by EVIL ;criminal entities for Profit only!

2 0 Reply • Share ›

Fisher153 → el Gallinazo
5 hours ago

Mercola has been clear on the dangers of the shots from day 1, referencing the dangers of antibody-dependent enhancement (ADE) early on. Many journals (and censorship agents, to include our hijacked federal govt) tried to refute him (e.g., Apr 2022, https://healthfeedback.org/... they were wrong, and their agendas have now been (are being) exposed. Dr. Mercola saved me and my family from this death shot and opened my eyes to the hijacking of the health industry. He provided us ACTUAL prophylactic and preventative health options. I thank God for using Dr. Mercola as a beacon of light and truth amidst the darkness of greed and totalitarian control.

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Voyt Regnal
4 days ago edited

PSYCHOPATHS in Canada calling for more Pfizer shots this fall....will it ever end?
https://www.cbc.ca/news/hea...

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Flora Flowers → Voyt Regnal
4 days ago

Canada is under communistic dictatorship.
They didn't resist
They are finished!

2 0 Reply • Share ›

TruthHunter → Voyt Regnal
3 hours ago

Not until people stop being so stupid and acting like sheeple, instead of people.

0 0 Reply • Share ›

Andreas
2 days ago

"In February 2021, Pfizer launched a randomized, placebo-controlled, observer-blind"

placebo-controlled, observer-blind - what does this mean , anybody? New terms mean Orwellian redefining to hide lowering the bar and not true science . . .

This appears to me as a false/misleading term to imply a true double blind placebo controlled study which FRK Jr pointed out that the vaccine developers don't do . . .
These guys compare one vax to another vax which is not a true Placebo, and articles like this conceal this intentional cover up when they list bullet points up front that imply "these are the starting point facts and universally accepted truths".

This is a magician's trick redirection - "we will tell you the issue, and its not about the study set up/validity of the methodology, focus on why it stopped". Why it stopped is a problem but lets also look at how all these vaxxes are tested and studied and you will find an epidemic failure of the scientific method and intentional fraud. Can't mix science and profiteering without the growth of corruption . . .

3 0 Reply • Share ›

Jerry Alatalo
3 days ago

Compared to the flu vaccine, COVID-19 shots were associated with a significant increase in adverse events including:

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Fetal chromosomal abnormalities
Fetal malformation
Fetal cystic hygroma
Fetal cardiac disorders
Fetal arrhythmia
Fetal cardiac arrest
Fetal vascular mal-perfusion
Fetal growth abnormalities
Fetal abnormal surveillance
Fetal placental thrombosis
Low amniotic fluid
Fetal death/stillbirth

see more

1 0 Reply • Share ›

TruthHunter
3 hours ago

They wanted, and want, de-population. Same reason Sanger joined the KKK (democrats) -- to kill all the black babies before they were born to stop the black families from reproducing. Demonic genocide.

0 0 Reply • Share ›

Fisher153
6 hours ago

"The FDA declined, stating that this information wouldn't be relevant."
The FDA, sold out to pharmaceutical interests, is no longer "relevant"; their rulings aren't worth the toilet paper on which they are written.

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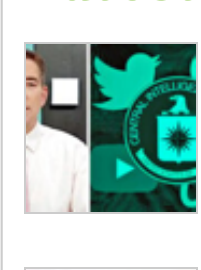

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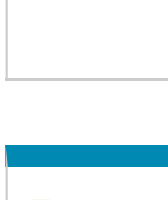

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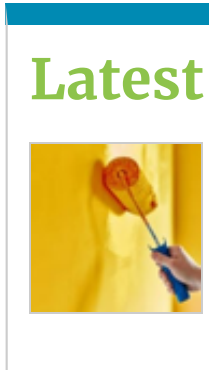

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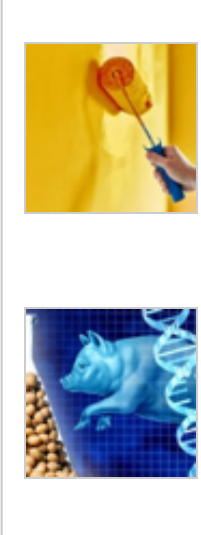

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